IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	09/981,248	Confirmation No.	6008
Appellant	:	Mark A. Hoffman, et al.		
Filed	:	10/16/2001		
Group Art Unit	:	1631		
Examiner	:	Marjorie A. Moran		
Title	:	COMPUTER SYSTEM FOR PROVIDING INFORMATION ABOUT THE RISK OF AN ATYPICAL CLINICAL EVENT BASED UPON GENETIC INFORMATION		
Atty. Docket No.	:	CRNI.83071		
Customer No.	:	**46169**		

VIA EFS – June 11, 2007

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

APPELLANTS' REPLY BRIEF

Dear Sir:

The following is Appellants' Reply Brief to the Examiner's Answer dated April 9, 2007. Having a two-month response date of June 9, 2007 (the 9th being on a Saturday), Appellants respectfully submit the following:

I. STATUS OF CLAIMS

Claims 25-30, 55-60, and 85-91 are the subject of this appeal. A complete listing is included in an appendix to this communication.

II. GROUNDS OF REJECTIONS TO BE REVIEWED ON APPEAL

Whether claims 25-27, 29-30, 55-57, 59-60, 85-87 and 89-91 are unpatentable under 35 U.S.C. § 103(a) over the ICHIKAWA reference (Internal Medicine (July 2000) Vol. 39, no. 7, pp. 523-524) in view of the EVANS reference (Science (Oct. 1999) Vol. 286, pp. 487-491) and the REINHOFF reference (U.S. Patent Application Publication No. 2002/0049772, filed 5/26/2000) and whether Claims 28, 58 and 88 are unpatentable under 35 U.S.C. § 103(a) as being unpatentable over the ICHIKAWA reference in view of the EVANS reference and the REINHOFF reference and in further view of FEY et al. (U.S. Patent Application Publication No. 2002/0038227, filed 2/26/2001).

III. ARGUMENT

Without diminishing their weight, Appellants' arguments in the Appeal Brief filed on October 3, 2006 and Supplemental Appeal Brief filed on November 20, 2006 are expressly incorporated by reference herein. For the sake of brevity, we focus on certain issues herein. But the absence of certain arguments should not be construed as any form of acquiescence unless expressly stated. When referring to "the invention" herein, we are referring to a claimed embodiment.

A. Rejection of Claims 25-27, 29-30, 55-57, 59-60, 85-87 and 89-91 under 35 U.S.C. §103(a)

Claims 25-27, 29-30, 55-57, 59-60, 85-87 and 89-91 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the ICHIKAWA in view of the EVANS and the REINHOFF. However, all of the cited references do not teach or suggest all of the claimed invention's features (in particular, outputting an interpretation of the genetic test result value and the list of risk-associated agents); and there is no motivation in the cited art for an ordinary skilled artisan to combine ICHIKAWA, EVANS and REINHOFF. Accordingly, the Office has failed to carry its burden of establishing a prima facie case of obviousness.

1. First Issue: At most, ICHIKAWA discusses that azathioprine treatment was discontinued due to leukopenia. Does this teach or suggest outputting an interpretation of the genetic test result value and the list of risk-associated agents?

The Office has relied upon Ichikawa for teaching the recitation of "outputting an interpretation of the genetic test result value and the list of risk-associated agents" of independent claims 25, 85 and 91 and the recitation of a computerized "outputting component that outputs an interpretation of the genetic test result value and the list of risk-associated agents" of independent

claim 55. The Examiner's Answer cites page 523, right column, second paragraph of ICHIKAWA for the teaching of the element for outputting an interpretation of the genetic test result value and the list of risk associated agents. The Examiner's Answer states that "[i]t would have been necessary for the physician and/or patient to have been made aware of the association in order to make the decision to discontinue treatment, and any type of communication is interpreted to be an 'output,' therefore teaching of ICHIKAWA makes obvious 'outputting' the results of a method associating polymorphism data, atypical clinical events, and risk-associated agents."

Appellants submit that the ICHIKAWA reference does not teach that the decision to discontinue treatment was made based on an association of a genetic test result value and an associated risk agent. To the contrary, the ICHIKAWA reference specifically states that "we sometimes experience marked leukopenia during the treatment with azathioprine, which forced us to stop use of the drug immediately." (ICHIKAWA, page 523, left column, paragraph 2) Furthermore, the ICHIKAWA reference merely states that "all three patients with the mutant allele of TPMT*3C discontinued azathioprine treatment due to leukopenia." (ICHIKAWA, page 523, right column, paragraph 2). The treatment is clearly stopped because of the leukopenia and not the awareness or output that the patient has the mutant allele TPMT*3C. The study, presumable conducted after the fact and completely independent of the care process, determined that the patients having the mutant allele had had their treatment stopped. There is no indication in the reference that the patient or physicians were aware that the patients had the allele for TPMT*3C when the treatment was discontinued due to leukopenia. In fact, if the output of the present invention was communicated, the drug/agent would not have been administered to the patient and the dangerous decrease in white blood cells (leukopenia) and increased risk of

disease would have been avoided. As such, there can be no teaching or suggestion of outputting an interpretation of the genetic test result value and the list of risk-associated agents. Furthermore, with respect to independent claim 55, there is no teaching or suggestion in ICHIKAWA of a computerized outputting component that outputs an interpretation of the genetic test result value and the list of risk-associated agents.

2. **Second Issue: At most, REINHOFF discusses that results of tests determining the presence or absence of various alleles are returned to a healthcare provider for communication to the individual. Does this teach or suggest outputting an interpretation of the genetic test result value and the list of risk-associated agents?**

The Office has also relied upon REINHOFF for teaching the recitation "outputting an interpretation of the genetic test result value and the list of risk-associated agents" of independent claims 25, 85 and 91 and the recitation of a computerized "outputting component that outputs an interpretation of the genetic test result value and the list of risk-associated agents" of independent claim 55. The Examiner's Answer cites paragraph 14 and 31 of REINHOFF for teaching the element of outputting an interpretation of the genetic test result value and the list of risk-associated agents. The Examiner's Answer states that "REINHOFF specifically teaches that results of computerized polymorphic profiling can be returned to a healthcare provider for communication to a tested individual (paragraph 31), which is a teaching for 'outputting' the results of a computerized method." However, paragraph 31 of REINHOFF states that results of the tests for determining the presence or absence of alleles predisposing an individual to a disease are returned to a healthcare provider. There is no teaching or suggestion of outputting a list of risk-associated agents. Furthermore, with respect to independent claim 55, there is no

teaching or suggestion in REINHOFF of a computerized outputting component that outputs an interpretation of the genetic test result value and the list of risk-associated agents.

Because neither ICHIKAWA nor REINHOFF, singularly or in combination, teach the last recitations of claims 25 and 55, the Office has not carried its burden of showing that prior-art references teach or suggest all elements of the claimed invention.

3. Third Issue: Is there motivation to combine REINHOFF, which discusses a known treatment, with ICHIKAWA and FEY, to determine a list of risk-associated agents for a genetic test result value for a person?

According the Examiner's Answer, Appellants have admitted in their Appeal Brief that there was a motivation to combine references (Examiner's Answer, Page 14). Appellants were merely quoting the Examiner from the Final Office Action (Page 4) dated September 8, 2005. Appellants have not admitted there is a motivation to combine and continue to maintain that there is no teaching or suggestion to combine the references.

The Examiner's Answer argues that "[t]he argument set forth on pages 8-9 of the Brief that one would not have been motivated to combine the references because the treatment of REINHOFF is already known does not appear to be germane to the claims as there is no limitation recited in the claims regarding "known" or "unknown" treatments or agents. Further, the agents (treatments) recited in the instant claims are necessarily "known" as they are found in the list of risk-associated agents which is accessed." (Examiner's Answer, page 8)

However, although the claims may not use the particular terms "known" and "unknown" , claims 25, 85 and 91 are directed to determining what risk-associated agents may be associated with a genetic test result value for a particular person. Thus, at the time the genetic test result value for a person is received the risk-associated agents that may affect the person based on the

genetic test result value are unknown. The computerized table listing polymorphism values and atypical clinical events is queried to determine if the genetic test result value received for the person is a polymorphism value associated with an atypical clinical event and a list of risk-associated agents associated therewith, thus making the risk-associated agents for the person "known."

There is no motivation to modify ICHIKAWA and EVANS or to combine ICHIKAWA and EVANS with REINHOFF exists. REINHOFF teaches a computer program product for separating individuals into subpopulations using a polymorphic profile in a networked environment. REINHOFF says that when a polymorphism is known to be associated with a response to a known treatment, this information may be used to allocate the most appropriate dose to subjects enrolled in a treatment study such as a clinical trial. (REINHOFF, Paragraph 0057). Appellants submit that one of skill in the art would not use REINHOFF as a motivation to computerize or automate accessing a list of risk-associated agents for a genetic test result value for a person and outputting the list of risk-associated agents because the treatment in REINHOFF is already known. As the treatment to be used in clinical trials as discussed in REINHOFF is already known, there is no need to access a list of risk-associated agents for a genetic test result value for a person and output the list of risk-associated agents.

IV. CONCLUSION

For at least the reasons stated above and those incorporated herein, independent claims 25, 55, 85 and 91 are believed to be in condition for allowance (and thus the corresponding dependent claims), and such favorable action is respectfully requested.

Respectfully submitted,

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